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RESEARCH PAPER

Relevant outcomes for nutrition interventions to treat and prevent malnutrition in older people: a collaborative senator-ontop and manuel delphi study

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Abstract

Background and aims Research in malnutrition in older people is limited by the lack of consensus on relevant outcomes. Researchers of two European initiatives, the 'Malnutrition in the Elderly (MaNuEL) Knowledge Hub' (mostly experts in nutrition) and the Optimal Evidence-Based Non-drug Therapies in Older People (ONTOP) project (geriatricians) agreed to merge forces performing a systematic review of the effectiveness of nutritional interventions for the prevention and treatment of malnutrition in older persons. In a first step, we aimed to identify relevant outcomes for this review using a systematic approach and to explore if the rating of relevant outcomes differed depending on the researchers' professional background.

Methods Following the ONTOP protocol, we searched all outcomes used in research of nutritional interventions for the prevention and treatment of malnutrition in older people. We carried out a web-based Delphi survey using a standardized list of 13 potentially relevant outcomes among 41 experts in geriatrics and nutrition who were asked to rate each outcome from 1 to 9 points: low importance (score 1–3), important but non-critical (score 4–6), and critical (score 7–9). Participants were informed that only those outcomes rated as critical (7–9 points) would be used in the literature review. After two rounds consultation, we compared the results from each group of experts: the ONTOP group formed by 13 geriatricians and the MaNuEL group formed by 28 experts in nutrition. Mean values were used for overall rating and the Mann–Whitney U test was used to see the differences on ratings between both groups.

Results Mortality, morbidity, functional status, nutritional status and quality of life were considered critical outcomes by the whole group of experts. However, by analysing the ratings by the experts' professional background, geriatricians only rated mortality, morbidity and functional status as critical, while experts in nutrition (MaNuEL group) rated nutritional status, changes in dietary intake, compliance with the intervention, quality of life, and frailty status outcomes as critical too. Two outcomes, changes in dietary intake and compliance with the intervention, were rated with a significant different between the two professional groups ($p < 0.05$).

Conclusions Five outcomes were considered critical for research in nutritional interventions for the prevention and treatment of malnutrition in older persons: mortality, morbidity, functional status, nutritional status and quality of life by the whole panel of experts. However, more consensus is needed on the relevance of specific outcomes of nutritional interventions. Consensus processes within but also between relevant organizations are required to reach consensus and to contribute to this aim.

Keywords Malnutrition · Elderly · Geriatrics · Critical outcomes · Nutritional interventions

Introduction

Malnutrition is considered one of the "geriatric giants", being a common problem in older people in any setting [1]. Malnutrition is associated with many negative health outcomes, including mortality [2, 3], morbidity, functional

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impairment, disability [4], reduced quality of life, and increased health care cost (hospitalizations, institutionalization) [5–7]. The relevance of these health outcomes may vary across the lifetime. The 2006 ESPEN Guidelines in Geriatrics acknowledged that, while reducing morbidity and mortality is a priority in younger patients, in geriatric patients maintenance of function and quality of life is often the most important aim [8].

Despite increasing scientific interest in malnutrition in older persons over the last decades, many uncertainties remain [9]: definition of malnutrition and the optimal screening tools [10] and the effectiveness of nutritional interventions [11, 12], for example. In 2016, within the European Joint Program Initiative "A healthy diet for a healthy life", the 'Malnutrition in the Elderly (MaNuEL) Knowledge Hub' was launched to support networking activities in this field [9]. One of the objectives of MaNuEL is to review the effectiveness of nutritional and other non-pharmacological interventions for the prevention and treatment of malnutrition in older persons. In parallel, a second European initiative, the Optimal Evidence-Based Non-drug Therapies in Older People (ONTOP) project, within the SENATOR trial (Software ENgine for the Assessment and optimization of drug and non-drug Therapy in Older persons; https://www.senator-project.eu/) [13, 14] is performing formal reviews of systematic reviews (SRs) on different geriatric syndromes, one of them being malnutrition [15]. Researchers of both groups decided to merge forces to perform this task. When planning the clinical questions to be used for the literature review using the PICO methodology [16], it became clear that there were different views on what were relevant outcomes of nutrition interventions for the prevention and treatment of malnutrition in older persons between researchers coming from the nutrition field and those working in clinical geriatric medicine. This fact could have a relevant impact in the selection of articles to be included in systematic reviews. Thus, in a first step, we aimed to identify relevant outcomes for this review using a systematic approach. In addition, we decided to explore if the rating of relevant outcomes differed depending on researchers' professional background.

Methods

To identify relevant outcomes for non-pharmacological nutrition interventions, following the ONTOP protocol, a web-based Delphi survey was carried out [17, 18].

First, a search of the most frequently used outcomes reported in clinical trials, systematic reviews and clinical guidelines of non-pharmacological interventions in older people with malnutrition or at risk of malnutrition was made in different databases (Pubmed, Embase, Cochrane library). A list of 13 outcomes was drafted (Table 1) and a survey spreadsheet was made. Experts were invited to complete the survey through an e-mail which contained a web-link to the survey. Two parallel surveys were sent to two different expert advisory panels. The first (ONTOP panel) was formed by 13 geriatricians from nine European countries (ES, FR, AT, IS, SE, BE, IE, GB, IT), who had been advising using the same methodology on relevant outcomes for other geriatric syndromes [19–22]. The second panel mostly formed by experts in geriatric nutrition (MaNuEL group) was formed by 28 researchers from seven European countries (ES, FR, AT, DE, CH, IE, NL) and New Zealand [9]. The experts who were invited to join the survey are listed in the acknowledgements. Free commercial software was used to create the online survey [23]. Stata v.12 was used to analyse and compare the answers from participants.

The same list of outcomes was sent to all participants (Table 1), asking them to rate each outcome from 1 to 9 points as follows: low importance (score 1–3), important but non-critical (score 4–6), and critical (score 7–9). An open box allowed proposing additional outcomes and giving comments. Participants were informed that only those outcomes rated as critical would be used in the literature review. A second round was launched with the same list of outcomes and the overall rating obtained for each outcome in the first round, so raters could hold or change their rating based on this feedback. The participants answered the survey anonymously.

Following the ONTOP protocol, overall rating from all participants was calculated by the mean and standard deviation, as it was previously assessed for other geriatric syndromes [19–22]. Mann–Whitney *U* test was used for comparison of the ratings between professional groups (geriatricians versus nutrition experts).

Results

From 13 experts of the ONTOP group and 28 from the MaNuEL group, 6 (46.1%) and 19 (67.9%) participated in the first round, and 5 (38.5%) and 14 (50.0%) in the second round. As the surveys were anonymous, it was not possible to know if participants from each group were the same between rounds. After first round consultation, morbidity and functional status were identified as critical (Table 1); no additional relevant outcomes were proposed, although some raters asked for clarifications of some of the terms used (e.g., nutritional status, difference between functional and frailty status, and difference between morbidity and adverse events). These clarifications were included in the outcome definition at the second round.

Table 1 Results of a first round Delphi survey to define critical outcomes of nutrition interventions for the prevention and treatment of malnutrition in older people

Potential outcomes	Geriatricians ($n = 6$) (mean ± SD)	Experts on nutrition ($n = 19$) (mean ± SD)	Total ($n = 25$) (mean ± SD)	Overall rate
Mortality[a]	7.0 ± 1.4	6.9 ± 1.8	6.9 ± 1.7	Important
Morbidity (hospital complications, infections, pressure sores…)	7.0 ± 1.1	7.7 ± 1.4	7.6 ± 1.4	Critical
Functional status	5.8 ± 2.8	8.0 ± 1.3	7.7 ± 1.5	Critical
Cognitive status	4.5 ± 2.2	5.8 ± 1.9	5.5 ± 2.0	Important
Nutritional status[b]	5.8 ± 2.5	8.3 ± 1.1	7.8 ± 1.3	Critical
Changes in dietary intake	5.3 ± 1.6	6.8 ± 2.1	6.5 ± 2.0	Important
Blood biomarkers (albumin, transferrin…)	4.3 ± 1.2	5.0 ± 1.8	4.8 ± 1.7	Important
Compliance with the intervention	4.2 ± 1.9	6.9 ± 2.1	6.3 ± 2.4	Important
Health care cost (LOS, admission to hospital/ nursing home…)	5.3 ± 1.0	6.0 ± 1.8	5.8 ± 1.6	Important
Falls	5.2 ± 1.2	5.7 ± 2.0	5.6 ± 1.9	Important
Quality of life[b]	5.7 ± 1.4	7.3 ± 1.6	6.9 ± 1.6	Important
Frailty status	4.8 ± 1.7	6.7 ± 1.2	6.3 ± 1.6	Important
Adverse events	4.8 ± 2.1	6.7 ± 1.5	6.2 ± 1.8	Important

n number of raters

[a]Only critical outcomes for geriatricians (ONTOP group)

[b]Only critical outcomes for the experts on nutrition (MaNuEL group)

Table 2 Results of a second round Delphi survey to define critical outcomes of nutrition interventions for the prevention and treatment of malnutrition in older people

Potential outcomes	Geriatricians ($n = 5$) (mean ± SD)	Experts on nutrition ($n = 14$) (mean ± SD)	Total ($n = 19$) (mean ± SD)	Overall rate
Mortality	7.4 ± 1.5	7.3 ± 1.1	7.3 ± 1.2	Critical
Morbidity (hospital complications, infections, pressure sores…)	7.4 ± 0.9	7.8 ± 1.1	7.7 ± 1.0	Critical
Functional status (mobility, ADL, physical performance…)	7.8 ± 0.4	7.4 ± 1.7	7.5 ± 1.4	Critical
Cognitive status (including dementia and delirium)	4.6 ± 1.8	5.7 ± 2.1	5.4 ± 2.0	Important
Nutritional status[a] (weight change, BMI, skin folds, muscle mass…)	6.8 ± 2.3	8.3 ± 0.9	7.9 ± 1.5	Critical
Changes in dietary intake[a]	5.0 ± 2.2	7.5 ± 1.8	6.8 ± 2.2	Important
Blood biomarkers (albumin, transferrin…)	5.8 ± 2.3	4.9 ± 2.0	5.1 ± 2.1	Important
Compliance with the intervention[a]	4.6 ± 2.5	7.3 ± 1.1	6.6 ± 1.9	Important
Heath care cost (LOS, admission to hospital/nursing home…)	6.2 ± 1.3	6.2 ± 1.6	6.2 ± 1.5	Important
Falls	6.0 ± 2.0	5.9 ± 2.0	5.9 ± 1.9	Important
Quality of Life[a]	6.2 ± 2.4	7.5 ± 0.9	7.2 ± 1.5	Critical
Frailty status[a] (changes in frailty scores)	5.0 ± 2.8	7.1 ± 1.5	6.5 ± 2.1	Important
Adverse events (diarrhoea, nausea…)	5.2 ± 2.4	6.9 ± 1.5	6.5 ± 1.9	Important

n number of raters

[a]Only critical outcomes for the experts on nutrition (MaNuEL group)

Table 2 shows the final rating of each outcome after the second round for the whole group and the two professional subgroups. More outcomes were rated as critical after the second round consultation. Mortality, morbidity, functional status, nutritional status and quality of life were considered critical by 15 (79%) experts and thus were selected to be used in the systematic review.

Ratings were different depending on the group of experts. Geriatricians only rated mortality, morbidity and functional status as critical, while experts on nutrition also rated nutritional status, changes in dietary intake, compliance with the intervention, quality of life, and frailty status as critical (Table 2).

Finally, nutritional status and quality of life obtained an overall mean enough to be rated as critical.

The sample size was too small to calculate kappa coefficients, so final rating dispersion was also calculated by median, 25th and 75th percentiles (Table 3). Mann–Whitney *U* tests showed significant differences between expert groups. Dietary intake and compliance with the intervention were considered as critical outcomes only by the nutritional experts from the MaNuEL group (Table 3).

Discussion

To make informed clinical decisions, patients and health care providers need to be aware of what outcomes are expected to change with any given intervention. When research or systematic reviews of research are planned, choosing relevant outcomes is key to make sound evidence-based recommendations.

Unfortunately, there is still little consensus on what are the relevant outcomes to be used in nutritional interventions for the prevention and treatment of malnutrition in older people. The 2006 ESPEN guidelines on geriatric nutrition suggested a list of outcomes that start in the provision of sufficient amounts of nutrients, move to maintenance or improvement of nutritional status, and finish in improving function, quality of life, morbidity and mortality [8].

Geriatricians (clinicians in care of complex older people) seem to focus on clinical outcomes. Possibly, they expect nutrition interventions to merge with other pharmacological and non-pharmacological interventions in improving the most relevant clinical outcomes (such as function, morbidity and mortality) and seem to be less interested in intermediate outcomes (such as nutritional intake and nutritional status) and thus in the mechanisms of action. On the other hand, the experts on nutrition while agreeing on those major clinical outcomes as relevant would also like to have nutrition-related intermediate outcomes confirmed (compliance with the nutritional intervention, changes in dietary intake, and changes in nutritional status) and also emphasize quality of life.

The main limitation of our study is the limited number of professionals included in this Delphi survey, and the fact that all of them are highly skilled professionals with research activities in older patients. They may not represent general geriatricians or non-geriatric focused nutritionists.

Table 3 Differences on second round outcome rating between geriatricians and experts on nutrition

Outcomes	Geriatricians ($n = 5$) P50 (P25, P75)	Experts on nutrition ($n = 14$) P50 (P25, P75)	p value
Mortality	8 (7, 8)	7 (6, 8)	0.70
Morbidity (hospital complications, infections, pressure sores…)	8 (7, 8)	8 (7, 9)	0.44
Functional status (mobility, ADL, physical performance…)	8 (8, 8)	8 (6, 9)	1.00
Cognitive status (including dementia and delirium)	4 (3, 6)	5 (5, 6)	0.32
Nutritional status (weight change, BMI, skin folds, muscle mass…)	7 (7, 8)	8,5 (8, 9)	0.10
Changes in dietary intake	6 (6, 6)	8 (7, 9)	0.02*
Blood biomarkers (albumin, transferrin…)	6 (6, 7)	5 (3, 6)	0.30
Compliance with the intervention	6 (3, 6)	7 (7, 8)	0.01*
Heath care cost (LOS, admission to hospital/nursing home…)	6 (5, 7)	6 (6, 7)	0.74
Falls	7 (5, 7)	6 (4, 7)	0.78
Quality of life	6 (5, 8)	7,5 (7, 8)	0.27
Frailty status (changes in frailty scores)	6 (2, 7)	7 (6, 9)	0.19
Adverse events (diarrhoea, nausea…)	6 (6, 6)	7 (6, 8)	0.18

n number of raters

*Significant differences between geriatricians and experts on nutrition based on *U* Mann–Whitney test

However, they do represent a wide range of European countries and different work environments and expertise.

Perhaps the most relevant conclusion is that five outcomes were consistently considered critical by the whole group of experts: mortality, morbidity, functional status, nutritional status and quality of life. These outcomes were also assessed in recent systematic reviews [24, 25]. Clear guidelines on which research outcomes to include and how to assess these specific outcomes, if issued by competent professional organizations, may foster nutrition research, comparability of research results and the ability to merge data in meta-analysis. This may be a crucial step in building solid evidence in the effectiveness of nutritional interventions in the future. Consensus processes within but also between relevant organizations are required to reach consensus and to contribute to this aim.

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Compliance with ethical standards

Conflict of interest Dr. Correa-Pérez reports Grants from EUROPEAN UNION FP7 PROGRAM (FP7/2007–2013) under Grant agreement no. 305930, during the conduct of the study; Dr. Cruz-Jentoft reports Grants from EUROPEAN UNION FP7 PROGRAM, during the conduct of the study; Dr. Volkert reports grants from Medical Nutrition Industrie (MNI), Grants from Nestlé Nutrition Institute, outside the submitted work; Dr. Lozano-Montoya has nothing to disclose; Dr. Visser has nothing to disclose.

Ethical standards The ONTOP-SENATOR project has been approved by the Ethics Committee from the coordinator site University College Cork (Cork, Ireland), and by the local Ethics Committee from the Hospital Universitario Ramón y Cajal (IRYCIS) (Madrid, Spain) where this work was conducted.

Informed consent For this type of study, informed consent is not required.

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